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10/506,564	09/03/2004	Emeric Gallard	0529-1038	3073

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EXAMINER	
PANI, JOHN	

ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,564	GALLARD ET AL.	
	Examiner	Art Unit	
	JOHN PANI	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 September 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/3/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “reconstruction in a three-dimensional visual space of the surface of the neural arch” of claim 2; the “four points delimiting a rectangle reproducing the vertebral body” of claim 6; the “points that correspond to the radiological indicators utilized to define the balance of the head of the patient with relation to the pelvis" of claim 7; the “at least ten points for the head allowing the external contour of the head to be marked” of claim 8; the “anatomical points…defining…the sacral plate” of claim 9; and the "at least three" points of the sacrum of claim 10 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: “LEV” and “UEV”. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: “VLS” and “VLI”.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claims 1, 2, 4-9, and 12-15 are objected to because of the following informalities:

In reference to Claim 1

In line 1 it is suggested to replace “the balance” with –balance--. In line 5 it is suggested to replace "consists" with --comprises--, because “consists” limits the claim to only the features specified within the claim and it appears based on subsequent dependent claims that the applicant intends to claim additional features. In line 6 it is suggested to replace "the relative" with --a relative--. In line 7 it is suggested to replace "the upper" with --an upper--. In line 10 it is suggested to replace “the radiographs” with –radiographs--. In line 12 it is suggested to replace “the position" with --a position--. In line 13 it is suggested to replace "the spinal segments" with --spinal segments--. In line 22 it is suggested to remove “(1)” and to replace "the vertical position" with --a vertical position--.

In reference to Claim 2

In line 6 it is suggested to replace "the geometry" with --a geometry--. In line 7 it is suggested to replace "the external envelope" with --an external envelope-". In line 10 it is suggested to replace "the surface" with --a surface-- and to replace "the neural arch" with --a neural arch--.

In reference to Claim 4

In line 4 it is suggested to replace "the front" with --front--.

In reference to Claim 5

In line 2 it is suggested to replace "the front" with --a front--. In line 5 it is suggested to replace "the position" with --a position--. In line 8 it is suggested to replace "the appearance" with –an appearance—and to replace "the reconstructed" with –a reconstructed—

In reference to Claim 6

In line 4 it is suggested to replace "the vertebral body" with --a vertebral body--.

In reference to Claim 7

In line 3 it is suggested to replace "the points" with ---points--. In line 4 it is suggested to replace "the radiological indicators" with –radiological indicators--. In line 5 it is suggested to replace "the head" with --a head--. In line 6 it is suggested to replace "the pelvis" with --a pelvis--.

In reference to Claim 8

In line 4 it is suggested to replace "the external" with –an external--.

In reference to Claim 9

In line 3 it is suggested to replace “the anatomical” with –anatomical--. In line 4 it is suggested to replace “the center” with –a center--. In line 5 it is suggested to replace “the sacral plate” with –a sacral plate--.

In reference to Claim 12

In line 3 it is suggested to replace “the geometric form” with –a geometric form--. In line 5 it is suggested to replace "the sagittal" with --sagittal--.

In reference to Claim 13

In line 3 it is suggested to replace "the linear" with --a linear--. In line 5 it is suggested to replace "the front" with --front--.

In reference to Claim 14

In line 4 it is suggested to replace “the front” with –a front--.

In reference to Claim 15

In line 5 it is suggested to replace “the projection” with –a projection--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 6-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In reference to Claims 6-15

The use of the term “consists of” renders the claims indefinite. A claim which depends from a claim which “consists of" the recited elements or steps cannot add an element or a step. See MPEP § 2111.03 [R-3].

In reference to Claim 10

It is unclear whether "the sacrum" in line 5 refers to "the sacral plate" of claim 9 line 5, or is another feature.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-5, 7, and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over “Frontal and sagittal balance analysis of late onset idiopathic scoliosis treated with third generation instrumentation” to Benli et al. (“Benli”) in view of “A three-dimensional radiographic comparison of Cotrel-Dubousset and Colorado instrumentation for the correction of idiopathic scoliosis" to Delorme et al. ("Delorme").

In reference to Claim 1

Benli teaches a method of viewing and controlling the balance of a vertebral column of which one spinal segment is corrected by means of conventional spinal instrumentation (pg. 232-233), characterized in that the method consists of: determining and calculating the relative position of the upper and lower end

instrumented vertebrae of the spinal segment corrected (see Fig. 1); determining and calculating the position of the spinal segments which are located above and below the spinal segment corrected by the spinal instrumentation according to the relative position of the three-dimensional position of the upper and lower end instrumented vertebrae (see Fig. 1, note that the position of all vertebrae are determined); and viewing the balance or imbalance of the vertebral column in the vertical position in front and side projection (pg. 234). However, Benli does not explicitly teach that the three-dimensional positions of the vertebrae are determined through anatomical points or contours identified or digitalized on the radiographs of the patient to be treated.

Delorme teaches a method of viewing the spinal column and analyzing the results of instrumentation for correcting scoliosis in which front and side radiographs are taken of the patient and are used to develop a three-dimensional reconstruction of the spine through anatomical points or contours identified on the radiographs (pg. 206-207). The front and side projections are viewed to view improvements in the shape of the spine (Fig. 1). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a method such as that taught by Delorme in which two dimensional radiographs are used to produce a three dimensional model of the spine in order to view the balance of the spine in the system of Benli, because as Benli teaches, scoliosis is a three dimensional deformation, and the instrumentation affects three dimensional changes which are best viewed through front and side projections of the three dimensional model, as taught by Delorme (see pg. 205).

In reference to Claim 2

Benli in view of Delorme teach the method of claim 1 (see above) and Delorme further teaches that the relative three-dimensional position of the upper and lower end instrumented vertebrae of the corrected spinal segment is obtained from a first reconstruction in a three-dimensional visual space of the geometry of the external envelope or contour of the upper and lower end instrumented vertebrae (see Fig. 1, includes contour of the vertebrae), and a second reconstruction in a three-dimensional visual space of the surface of the neural arch of the upper and lower end instrumented vertebrae (see Fig. 2, includes neural arch/pedicles).

In reference to Claim 3

Benli in view of Delorme teach the method of claim 2 (see above) and further Delorme allows that the relative position of the upper and lower end instrumented vertebrae of the corrected spinal segment be determined in a three dimensional space (see Figs. 1 and 2).

In reference to Claim 4

Benli in view of Delorme teach the method of claim 3 (see above) and further teach that the upper and lower end instrumented vertebrae of the spinal segments are projected on front and side radiographs of the patient to be treated (Note that Figs. 1 and 2 of Delorme are deemed "radiographs of the patient to be treated", and are “projections” of a three dimensional model onto a two dimensional plane. Benli in Fig. 1 teaches that all of the vertebrae are considered).

In reference to Claim 5

Benli in view of Delorme teach the method of claim 4 (see above) and further teach that the front and side projection of the upper and lower end instrumented vertebrae of the corrected spinal segment allows the position on the front and side radiographs of the spinal segments located above and below the corrected spinal segment to be determined and to view the appearance of the reconstructed vertebral column on the front and side radiographs (see Figs. 1 and 2 of Delorme, the relative positions are depicted therein).

In reference to Claim 7

Benli in view of Delorme teach the method of claim 1 (see above) and Delorme teaches digitalizing points that correspond to radiological indicators utilized to define the balance of the head of the patient with relation to the pelvis (Note that in the method of Benli, vertebrae are used to determine balance, and Delorme digitalizes the contours of the vertebrae).

In reference to Claim 11

Benli in view of Delorme teach the method of claim 1 (see above) and Delorme further teaches embedding the digitalized points in the radiographs of the patient (the 3-D radiographs include a wire frame of the surface of the vertebrae thus including the digitalized points).

In reference to Claim 12

Benli in view of Delorme teach the method of claim 1 (see above) and Delorme further teaches that the method consists of reconstructing the geometric form of all the vertebrae in three dimensions from sagittal and frontal radiographs of the patient (see

pg. 206, paragraph 5 under “Materials and Methods", particularly reference 2, which is attached with this Action).

In reference to Claim 13

Benli in view of Delorme teach the method of claim 1 (see above) and Delorme further teaches determining the linear and angular geometric position of all the vertebrae, including the upper and lower instrumented, with relation to the front and side radiographs (see Figs. 1-2).

In reference to Claim 14

Benli in view of Delorme teach the method of claim 1 (see above) and Delorme further teaches projecting all the vertebrae, including the upper and lower instrumented, on the front and side radiographs (see Figs. 1 and 2).

In reference to Claim 15

Benli in view of Delorme teach the method of claim 1 (see above) and Delorme further teaches embedding the projection of the upper and lower end instrumented vertebrae in radiographs with relation to one another by registration of the projection of the lower end instrumented vertebrae (the projection views in Figs. 1 and 2 include data embedded therein with relation to one another, and the various vertebrae including the lower end instrumented, are registered in that projections are set to the same scale in the various views).

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Benli in view of Delorme as applied to claim 1 above, and further in view of US 2002/0061126 to Gerard et al. ("Gerard").

In reference to Claim 6

Benli in view of Delorme teach the method of claim 1 (see above) but do not teach identifying at least four points delimiting a rectangle reproducing the vertebral body for each vertebrae of the vertebral column. Gerard teaches a method for reconstructing the spinal column from radiographs in which four points are used to delimit a rectangle, in addition to other points for the pedicles (see Figs. 2A and 2B and [0015-0059]). It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted Gerard's method of forming a three-dimensional reconstruction of the spine for that of Delorme because the substitution of one known method of three-dimensional spine reconstruction for another would achieve the predictable result of providing information appropriate to help diagnose scoliosis as taught by Delorme (pg. 205) and Gerard (see [0005]).

8. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benli in view of Delorme as applied to claims 1 and 7 above, and further in view of "Reconstruction radiographique 3D personnalisée du bassin humain" to Gauvin et al. ("Gauvin").

In reference to Claims 9-10

Benli in view of Delorme teaches the method of claim 1 (see above), and Benli mentions determining the mid-sacral line, but does not mention identifying or digitalizing at least the anatomical points for the pelvis defining the center of each femoral head and the sacral plate, nor identifying or digitalizing at least five points for the pelvis of which one is for each femoral head and at least three are for the sacrum in order to form a triangle. Gauvin teaches a method in which the pelvis, spine, and ribs are three dimensionally reconstructed in order to help in the diagnosis of curvature of the spine (see Summary). Five points are identified for the pelvis including one for each femoral head (18, 19) and three for the sacrum (4, 5, and 11, for example) and form a triangle (see Fig. 1). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the method of Benli in view of Delorme by including a three-dimensional reconstruction of the pelvis in the radiological model in order to more realistically simulate the biomechanics of the body as taught by Gauvin, and to provide a more detailed method of determining the midsacral line.

In reference to Claim 8

Benli in view of Delorme teaches the method of claim 7 (see above) but does not teach that the method includes identifying or digitalizing at least ten points for the head allowing the external contour of the head to be marked. Benli teaches that the shift of the head is an important parameter in balance analysis (pg. 234), but uses the position of the seventh cervical vertebra as a proxy for the position of the head.

Gauvin teaches using multiple points to determine the contours of large anatomical features which contribute to the biomechanics of the spine (see rejection of

claims 9-10 above). It would have been obvious too one having ordinary skill in the art at the time of the invention to have modified the method of Benli in view of Delorme by substituting a representation of the head for the mid point of the seventh cervical vertebra as this would more accurately depict the position of the head, and to do so by digitizing points on the surface (including 10 or more) as this provides an accurate depiction of large three dimensional anatomical features as taught by Gauvin.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

"Optimized vertical stereo base radiographic setup for the clinical three-dimensional reconstruction of the human spine" to Andre et al. is reference 2 in the Delorme reference and describes in detail a three-dimensional reconstruction of the spine based on two two-dimensional radiographs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JP 6/17/08

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736